

Under 37 C.F.R. § 1.76(b)(5), this specific reference to the priority claim in the Application Data Sheet is sufficient, and need not be presented elsewhere in the specification. Therefore, Applicant respectfully submits that the application already includes the required reference to the priority claim, so no amendment is required.

Provisional Rejection of Claims 1-41 for Obviousness-Type Double Patenting

Claims 1-41 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-20 of co-pending Application No. 10/285,016. As this is a provisional rejection, Applicant will not address it further at this time.

Rejection of Claims 20, 22-23, and 36 under 35 U.S.C. § 102(b)

Claims 20, 22-23, and 36 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Slutsky et al., U.S. Patent No. 6,102,036 (“Slutsky”).

Applicant’s claims 20 and 36 are directed to an oral nicotine delivery device and method for orally administering a nicotine solution.

Slutsky discloses a nicotine inhaler for administering nicotine by inhalation and absorption in the lungs. The reference does not teach oral delivery of a nicotine solution.

To anticipate a claim, a reference must teach every element of the claim. MPEP § 2131. Slutsky does not teach every limitation of claims 20 or 36 because the reference does not teach an oral delivery device or method for administration of nicotine orally. In contrast, Slutsky continually emphasizes that the disclosed device and the nicotine preparation it contains are adapted specifically for administration of nicotine by inhalation and rapid absorption in the lungs (e.g., column 3, lines 34-46; column 6, lines 5-15). Furthermore, Slutsky does not teach delivery of nicotine as a solution. On the contrary, Slutsky states that “[t]he breath activated inhalers of the invention deliver . . . nicotine into the alveoli and small airways, in a particulate form which is sized for rapid absorption” (emphasis added) (column 6, lines 6-9). Moreover, Slutsky emphasizes the drawbacks of nicotine solutions, stating that “nicotine in a solution has an alkaline pH which irritates the throat and upper airways” (column 3, lines 5-6).

Thus, as Slutsky does not teach every limitation of Applicant’s claims 20 or 36, it does not anticipate claim 20, claim 36, or dependent claims 22-23, which are drawn to embodiments of claim 20 and thus contain every limitation of claim 20. Accordingly, Applicant respectfully

submits that the present rejection of claims 20, 22-23, and 36 under 35 U.S.C. § 102(b) should be reconsidered and withdrawn.

Rejection of Claims 1-9 and 13-15 under 35 U.S.C. § 103(a)

The Examiner rejected claims 1-9 and 13-15 under 35 U.S.C. § 103(a) as being obvious over Wong et al., U.S. Patent No. 6,106,845 (“Wong”) in view of Ruecroft et al., U.S. Patent No. 5,663,356 (“Ruecroft”).

Applicant’s claims 1-9 and 13-15 are directed to a tubular delivery device and method for oral administration of nicotine.

Wong discloses an oral active agent delivery system for delivering discrete units of an active agent formulation to a patient. The reference does not teach or suggest that the active agent is nicotine.

Ruecroft is directed to methods for preparing aryl substituted olefinic secondary amine compounds. Ruecroft teaches that nicotine has been proposed to have a number of pharmacological effects, and reportedly potentiates the pharmacological behavior of certain pharmaceutical compositions used to treat central nervous system disorders (column 1, lines 39-40 and 62-65). Ruecroft does not disclose any delivery device for nicotine.

To support a *prima facie* case of obviousness, the cited references must teach or suggest every element of the claimed invention, and there must be some suggestion or motivation to combine the teachings of the cited references. The motivation to combine must be found in the prior art, and must not be based on impermissible hindsight in view of Applicant’s disclosure. MPEP § 2142.

Neither of the cited references alone teaches or suggests every limitation of any of Applicant’s claims 1-9 or 13-15. Wong does not teach or suggest a delivery device containing nicotine. Ruecroft mentions nicotine but does not teach or suggest any type of delivery device. Furthermore, as recognized by the Examiner, neither reference teaches or suggests the particular doses of nicotine recited in Applicant’s dependent claims 9 and 14-15.

Moreover, there would have been no motivation to combine the teachings of Wong, relating to particular medication delivery devices, with the teachings of Ruecroft, directed to methods of preparing certain nicotine-related compounds. No motivation to combine would exist because the two references belong to distinct and unrelated fields, namely, medical delivery

devices and synthetic chemistry. The Examiner asserted that Wong teaches that the active agent included in the disclosed delivery device can be one of a large number of substances that have a pharmacologic effect, including drugs that act on the central nervous system, and that Ruecroft teaches that nicotine has pharmacological effects and has been used in the treatment of neurological disorders. This alleged connection between the two references would only be drawn based on improper hindsight in view of Applicant's disclosure. There simply is nothing in the disclosure of Wong that would cause one of skill in the art to focus even on the general class of central nervous system drugs from among the laundry list of potential active agents presented. Moreover, Wong effectively teaches away from the use of nicotine as the active agent by stating that the disclosed delivery device is particularly useful for delivering large doses of medication to patients who have difficulty swallowing capsules or tablets (*see, e.g.*, column 1, lines 32-43; column 3, lines 33-40; column 7, lines 48-50). Therapeutically effective doses of nicotine are generally small enough that they would fit into a small tablet that would not be difficult to swallow. Therefore, there would be no motivation to use the device of Wong to deliver nicotine. Furthermore, nothing in the disclosure of Ruecroft suggests that its teachings regarding nicotine would have any applicability with respect to drug delivery devices. Thus, the only possible motivation to combine the teachings of Wong and Ruecroft would be due to improper hindsight in view of Applicant's disclosure.

Accordingly, because neither of the cited references alone teaches or suggests every limitation of any of claims 1-9 or 13-15, and there would have been no motivation to combine the cited references, *prima facie* obviousness has not been established.

Furthermore, even if a *prima facie* case of obviousness had been established, it would be rebutted by the unexpected results presented in the attached Declaration of the inventor Barbara S. Fox, Ph.D. As explained and demonstrated by experimental evidence presented in the Declaration, a device and method as claimed provides unexpected synergistic benefits beyond what would be expected from simply combining teachings from the prior art. In particular, the evidence presented in the Declaration demonstrates that a device and method as claimed reduced cigarette cravings more than would be expected by adding the craving reduction produced by the nicotine alone to the craving reduction produced by the identical device without the nicotine. This synergistically improved ability to reduce cigarette cravings promotes the effectiveness of the claimed devices and methods as smoking cessation aids.

Thus, *prima facie* obviousness has not been established, and even if it were established, it would be rebutted by the unexpected improved results provided by the claimed devices and methods. Accordingly, claims 1-9 and 13-15 are not obvious in view of the cited references alone or in combination, and Applicant respectfully requests that the present rejection of claims 1-9 and 13-15 under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

Rejection of Claims 10-12 and 16-41 under 35 U.S.C. § 103(a)

The Examiner rejected claims 10-12 and 16-41 under 35 U.S.C. § 103(a) as being obvious over Wong in view of Ruecroft, and further in view of Westman et al., U.S. Patent No. 6,211,194 (“Westman”).

Applicant’s claims 10-12 and 16-41 are directed to a delivery device and method for oral administration of nicotine. The delivery device has a tubular chamber containing a nicotine granulate (claims 10-12 and 16-19) or nicotine solution (claims 20-41) and a retainer for preventing release of the nicotine from one end of the chamber. The other end of the chamber is suitable for oral application of suction, and nicotine is delivered through that end of the chamber when oral suction is applied.

The teachings of Wong and Ruecroft are described above. Ruecroft mentions nicotine but does not teach or suggest any type of delivery device. Wong does not teach or suggest a delivery device containing nicotine. Furthermore, the device of Wong includes solid or particulate “discrete units” of an active agent that may be delivered in admixture with an external fluid (*see, e.g.*, column 1, lines 11-22; column 2, lines 10-16; column 3, lines 15-20). Wong does not teach or suggest that the device itself contains a solution of active agent (*e.g.*, nicotine), as recited in claims 20-41, and indeed teaches away from a device containing a solution by referring to the “shelf-life problems encountered when a medicine is dissolved or dispersed in a fluid” (column 2, lines 5-6).

Westman discloses a solution containing nicotine. Westman does not teach or suggest an oral delivery device having a tubular chamber that contains a nicotine granulate or nicotine solution and a retainer for preventing release of the nicotine from one end of the chamber, with the other end of the chamber suitable for oral application of suction, such that nicotine is delivered through that end of the chamber when oral suction is applied. Thus, none of the cited references alone teaches or suggests every element of Applicant’s claimed invention.

Furthermore, there would have been no motivation to combine the teachings of Wong, relating to particular delivery devices, with the teachings of Ruecroft, directed to methods of preparing certain nicotine-related compounds, or the teachings of Westman, relating to nicotine solutions. No motivation to combine would exist because the references are directed to unrelated subjects, namely, medical delivery devices, synthetic chemistry, and nicotine formulations for treating conditions such as smoking tobacco addiction. Furthermore, as discussed above, Wong teaches away from the use of solutions, such as that of Westman. Thus, the only possible motivation to combine the cited references would be based on improper hindsight in view of Applicant's disclosure.

Therefore, because there would have been no motivation to combine the cited references, *prima facie* obviousness has not been established. Furthermore, as described in detail above, even if a *prima facie* case of obviousness had been established, it would be rebutted by the unexpected results presented in the attached Declaration of Barbara S. Fox, Ph.D.

Accordingly, as claims 10-12 and 16-41 are not obvious in view of the combination of cited references, Applicant respectfully requests that the present rejection of claims 10-12 and 16-41 under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

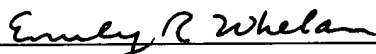
CONCLUSION

In view of the arguments set forth herein and the evidence presented in the accompanying Declaration of Barbara S. Fox, Ph.D., Applicant respectfully submits that the rejections contained in the Office Action mailed on May 7, 2003 have been overcome, and that all of the pending claims are in condition for allowance.

No fees are believed to be due in connection with this correspondence. However, please charge any payments due or credit any overpayments to our Deposit Account No. 08-0219.

The Examiner is encouraged to telephone the undersigned at the number listed below in order to expedite the prosecution of this application.

Respectfully submitted,



Emily R. Whelan
Reg. No. 50,391

Dated: 8/1/03

HALE AND DORR LLP
60 State Street
Boston, MA 02109
617-526-6567 (telephone)
617-526-5000 (facsimile)